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42715 7590 07/14/2009

BUCHANAN INTELLECTUAL PROPERTY OFFICE LLC
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PERRYSBURG, OH 43552-0700

EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3774

DATE MAILED: 07/14/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,716

08/30/2004

Brian C. Case

1000-130

4764

TITLE OF INVENTION: ARTIFICIAL VALVE PROSTHESIS WITH IMPROVED FLOW DYNAMICS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	10/14/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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42715 7590 07/14/2009

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,716	08/30/2004	Brian C. Case	1000-130	4764

TITLE OF INVENTION: ARTIFICIAL VALVE PROSTHESIS WITH IMPROVED FLOW DYNAMICS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	10/14/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
STEWART, ALVIN J	3774	623-001240

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,716	08/30/2004	Brian C. Case	1000-130	4764
42715	7590	07/14/2009	EXAMINER	
BUCHANAN INTELLECTUAL PROPERTY OFFICE LLC P.O. BOX 700 PERRYSBURG, OH 43552-0700			STEWART, ALVIN J	
			ART UNIT	PAPER NUMBER
			3774	
DATE MAILED: 07/14/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 407 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 407 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/828,716	CASE ET AL.	
	Examiner	Art Unit	
	Alvin J. Stewart	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on 04/30/09 and interview made 06/11/09.
2. ☒ The allowed claim(s) is/are 11, 12, 22 and 30-32 (renumbered as 1-6).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
|---|--|

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Matthew Buchanan on 06/11/09.

The application has been amended as follows:

AMENDMENTS TO THE CLAIMS

Claims 2-10, 14, 15 and 18-20 are cancelled.

In claim 11, line 1 number "10" has been replaced by number ---22---.

22. (currently amended) A radially expandable artificial valve prosthesis for implantation in a vessel having a vessel wall comprising:

a support structure having a longitudinal axis, a first end that includes a first and a second commissure, and a second end located distal thereto, the first and second commissures disposed substantially opposite each other with respect to the longitudinal axis, the support structure defining first and second attachment pathways, the first attachment pathway including a first proximal portion extending from the first commissure, a second proximal portion extending from the second commissure, [and] a first distal portion angling obliquely from the first proximal portion and a second distal portion angling obliquely from the second proximal portion, the first and second distal portions cooperatively [and second proximal portions and] defining a first distal commissure at the second end of the support structure, the second attachment pathway including a third proximal portion extending

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from the first commissure, a fourth proximal portion extending from the second commissure, [and a second] a third distal portion angling obliquely from the third proximal portion and a fourth distal portion angling obliquely from the fourth proximal portion, the third and fourth distal portions cooperatively [and fourth proximal portions and] defining a second distal commissure at the second end of the support structure, the first, second, third, and fourth proximal portions extending along a substantial portion of the length of the prosthesis and having a substantially parallel orientation with respect to the longitudinal axis of the support structure, the first and second distal commissures disposed substantially opposite each other with respect to the longitudinal axis;

a plurality of leaflets, each leaflet of the plurality of leaflets having an outer edge that includes a first lateral edge extending distally from the first commissure and a second lateral edge extending distally from the second commissure, the first and second lateral edges generally converging about the second end of the support structure such that the plurality of leaflets is configured to collectively form a seal with said vessel wall and restrict fluid flow through said vessel; and

wherein the first and second lateral edges of a first leaflet of the plurality of leaflets are each attached to the support structure along the first attachment pathway and the first and second lateral edges of a second leaflet of the plurality of leaflets are each attached to the support structure along the second attachment pathway such that each leaflet of the plurality of leaflets has a coaptable area and a basal portion, the coaptable area and basal portion configured to cooperate with said vessel wall to define a valve pocket;

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wherein the coactable areas of the plurality of leaflets are configured to coapt with each other while said valve prosthesis is in a resting state and wherein each coactable area of each leaflet of the plurality of leaflets has a length that is between 10% and 80% of the length of said valve prosthesis.

AMENDMENTS TO THE SPECIFICATION

[0042] FIGS. 9,11, and 13-20 comprise embodiments of an artificial valve prosthesis 10 in which support structure 11 carrying the leaflets 26 is configured to increase the leaflet contact (coactable) area 57 about the proximal portion of the valve structure 12 without relying on built-in slack within the material to bring the leaflets in closer proximity and provide for a extensive sealing area, longitudinally. As defined in this application, the leaflet contact area 57 comprises a longitudinal portion along the valve structure 12 in which the facing surfaces of opposing leaflets 26 (two or more) coapt or lie in close proximity to one other while in a dry or resting, neutral state (i.e., the pressure differentials across the valve orifice are essentially equalized such that the leaflets are not being forced together or apart due to external forces, such as fluid flow), when the prosthesis is an expanded or deployed configuration. The support frame 11 may be configured for maximizing the extent of the leaflet contact area 57 by including one or more longitudinal attachment struts 49,50 that define at least the proximal portion 75 of the attachment pathway 74 of each leaflet lateral outer edge 87,88 (the terms outer edge 39 and lateral outer edges 87,88 being defined herein as the area or zone along the leaflet that comprises the sealing interface). The longitudinal attachment struts 49,50/proximal attachment pathways 75 have a substantially longitudinal

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orientation (e.g., substantially parallel) with respect to the longitudinal axis 64 of the prosthesis (and valve structure 12). At a point generally proximate the distal end 89 of the leaflet contact area 57 (the proximal portion 96 of the leaflet), the distal portions 76 of the adjacent attachment pathways 74 (which are joined proximally about a commissural point) diverge from one another (forming a generally Y-shaped pathway configuration) and assume a much more circumferential orientation than that of the proximal portion 75 of the pathway such that the outer leaflet lateral edges 87,88 of each leaflet converge at a point lateral to the free inner edge 84 thereof to seal the passageway and form the distal portion 96 of the leaflet that defines the bottom 96 or `floor` of the pocket 55 or intravascular space adjacent the outer surfaces of each of the leaflets, which generally assumes a strongly cupped or curved shape such that the leaflet assumes a generally `folded` appearance due to the acutely angled attachment pathway 74 with the proximal portion of the leaflet having a strong longitudinal orientation with respect to the prosthesis and vessel and the bottom portion 96 having a strongly perpendicular orientation relative to the longitudinal axis of the vessel and prosthesis. Thus, each of the attachment pathways 74 includes a proximal portion 75 that comprises a substantial portion of the length of the prosthesis 10 and has primarily a longitudinal orientation with respect to the longitudinal axis 64 of the prosthesis 10, and a distal portion 76 that angles obliquely from the proximal portion 75. As best illustrated in Figure 14, a first attachment pathway includes a first proximal portion 50 extending from the first commissure 27, a second proximal portion 49 extending from the second commissure 28, a first distal portion angling obliquely from the first proximal portion 50 and a second distal portion angling obliquely from the second proximal portion 49. The first and second distal portions cooperatively define a first distal commissure at the second end of the

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support structure 11. Similarly, a second attachment pathway includes a third proximal portion extending from the first commissure, a fourth proximal portion extending from the second commissure, a third distal portion angling obliquely from the third proximal portion and a fourth distal portion angling obliquely from the fourth proximal portion. The third and fourth distal portions cooperatively define a second distal commissure at the second end of the support structure 11. It should be noted that the commissures 27,28, while located about the proximal end 13 of the illustrative prosthesis 10, may be located proximal thereto such that additional support structure 10 extends proximally, such as in the embodiments of FIGS. 2-8,12.

Claim 22 is allowable. The restriction requirement with respect to claims 11 and 12 filed on 02/12/07, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 11 and 12 are directed to the elected species no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Allowable Subject Matter

Claims 11, 12, 22 and 30-32 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

June 12, 2009.